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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/658,326 | 09/10/2003 | Andreas Steinmeyer | SCH-1585D3 | 1878 |

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| EXAMINER | |
|---|---|
| QAZI, SABIHA NAIM | |
| **ART UNIT** | **PAPER NUMBER** |
| 1616 | |

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/658,326 | STEINMEYER ET AL. | |
| | Examiner | Art Unit | |
| | Sabiha Qazi | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *26 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *11-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *11-26,33 and 34* is/are allowed.

6)☐ Claim(s) *27-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

**Final Office Action**

Acknowledgement is made of the response filed on 1/26/2006. Amendments are entered. Claims 11-42 are pending. Claims 11-26, 33 and 34 is the elected invention of group I which is allowed. Claims 27-32 and 35-42 are drawn to method claims.

***Allowable Subject Matter***

1. Claims 11-26, 33 and 34 are allowed. Closest prior art is WO 97/41096. Prior art does not teach nor suggest the substitution of phenyl group at C-25 (Z).

2. Rejoinder of Method claims

*3.* When the invention of group I would be allowed the methods of group II would be rejoined with the compounds of invention of group I.

In order to be eligible for rejoinder, a claim to a nonelected invention must depend from

or otherwise require all the limitations of an allowable claim. A withdrawn claim that does not require all the limitations of an allowable claim will not be rejoined. Furthermore, where restriction was required between a product and a process of making and/or using

the product, and the product invention was elected and subsequently found allowable, all

claims to a nonelected process invention must depend from or otherwise require all the

limitations of an allowable claim for the claims directed to that process invention to be

eligible for rejoinder. See MPEP § 821.04(b).

Until elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claim that are not commensurate in scope with an allowed product will not be rejoined. See "Guidance on Treatment of Product and process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103 (b)," 1184 O.G. 86 (March 26, 1996).

In order to retain the right to rejoinder,

applicant is advised that the claims to the nonelected invention(s) should be amended

during prosecution to require the limitations of the elected invention. Failure to do so

may result in a loss of the right to rejoinder.

Rejoined claims must be fully examined for patentability in accordance with 37 CFR

1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112.

See also MPEP § 804.01.

Response to Remarks

- Applicant's arguments were fully considered but are not found persuasive because claims are broad and still contain enablement issues. See for example in claim 30, "intoxication with calcitriol or its analogues", claim 27 "AIDS", "and/or neurodegenerative of peripheral and central nervous system". These are few examples.
- In order to retain the right to rejoinder, Applicant must amend the claims. See the reasons cited above.

**Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-32 and 35-42 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain diseases, does not reasonably provide enablement for the treatment of all the disease as claimed. Claims are drawn to the treatment of AIDS, Alzheimer's and various other diseases by vitamin D compounds. Since these diseases are not treated by vitamin D compounds

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these

factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

Claims are rejected because there is a lack of enablement for the method for treatment of the diseases listed in the claims.

***The nature of the invention***

Presently claimed invention is drawn to a method for treatment of various diseases as in claims 27-32

Hyperproliferation and deficient cell differentiation

- Disequilibrium of the immune system
- Steroid induced osteporosis
- Senile osteoporosis
- Degenerative diseases of the peripheral and central nervous system
- Melanomas
- Betazell carcinoma
- Squamous carcinoma
- Actinic keratoses
- Cervix dysplasias
- Tumors of intestine
- Carcinoma of breast
- Acne
- Lung tumors
- Prostate carcinomas
- Leukemias
- Ichthyosis

- Prutitus
- Inflammatory disease
- Eczema
- Disease of the Atropic Formon series
- Rheumatoid arthritis
- Asthma
- Respiratory tract disease
- An autoimmune disease
- Multiple sclerosis
- Diabetes mellitus type I
- AIDS
- Rejection in case of autologous, allogeneic or Xenogeneic transplants

and many more.

***The predictability or unpredictability of the art:***

There is a general lack of predictability in the pharmaceutical art. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970). Therefore predicting the method of treating or inhibiting various disease states by compounds of broad genus of vitamin D is impossible. For example MIYAMOTO et al. (US Patent 6,124,276) discloses vitamin D compounds useful the treatment of osteoporosis, and as antitumor agent. Steinmeyer et al. (WO 97/41096 and WO 94/00428) discloses vitamin D compounds useful for the treatment of osteoporosis and hyperproliferative skin diseases. DeLuca et al. (US Patent 6,127,559) discloses the use of vitamin D compounds for treatment of psoriasis, osteoporosis and for certain cancers. Reddy (US Patent 6,479,538) discloses various vitamin D compounds useful for inhibiting the proliferation and/or inducing the differentiation of a hyperproliferative skin cell. DeLuca et al. (US Patent 5,945,410) discloses the method of treatment for metabolic bone disorder. However, none of them teaches the treatment of AIDS or Alzheimer's disease by vitamin D compounds.

IT is therefore impossible to predict the treatment of certain diseases such as AIDS or Alzheimer's diseases in this case.

***The amount of direction or guidance presented***

A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See *In re Riat* et al. (CCPA 1964) 327 F2d 685, 140 USPQ 471; In re Barr et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result".

See *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity).

See also In re Wright, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991), this is because it is not obvious from the disclosure of one species, what other species will work.

***The presence or absence of working examples***

There no examples or test data in vivo or in vitro to support all the methods of treatment as presently claimed. In the disclosure on page 25 Applicant disclose that the compounds of the invention are suitable for the treatment of listed diseases.

On page 26, the increase in thickness of the epidermis is described on skin of mice. On page 28 it states, "In addition, it has been found that certain compounds of general formula I in HL 60 cells

***The quantity of experimentation necessary***

Since different aspects of biological activity cannot be predicted but must be determined from the case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue experimentation study.

Since the nature of the method is so unpredictable, and since the claims are drawn to a broad range of pharmaceuticals for treatment of such a broad range of diseases such as AIDS, Azhiemer's and since there is a lack of guidance present in the specification, the skilled artisan would have to undertake undue experimentation to practice the claimed invention commensurate with the scope of the claims.

***Conclusion***

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Padmanabhan, Sreeni (acting) can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saturday, April 15, 2006

SABIHA QAZI, PH.D
PRIMARY EXAMINER